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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,655	07/31/2001	Peter Boekstegers	07883.0046	1083

7590 05/10/2004

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Washington, DC 20005-3315

EXAMINER

THANH, QUANG D

ART UNIT	PAPER NUMBER
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3764

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DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,655

Applicant(s)

BOEKSTEGERS ET AL.

Examiner

Quang D. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6-8, 10-22, 24-31, 33-35 and 37-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-8, 10-22, 24-31, 33-35 and 37-48 is/are rejected.
- 7) ☒ Claim(s) 24, 43, 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/2004 has been entered. Claims 2,5,9,23,32, and 36 have been canceled, and currently claims 1,3,4,6-8,10-22,24-31,33-35 and 37-48 are pending.

Claim Objections

2. Claims 24, 43, 46 are objected to because the limitation " the flared end" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,3,4,6-8,10-22,24-31,33-35, 38-40,42,43,45,46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al. (6,406,488) in view of Tedeschi et al. (6,361,819).

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5. Re claims 1, 6-8, 17, 21-22, 29, 33-35, Tweden discloses a device and a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract), comprising: providing a stent 10 (portions 13 and 14) (fig. 1) having sufficient strength to resist deformation from contractile cardiac forces (col. 2, lines 49-51) and remain patent when implanted in a myocardial site (fig. 1), and having a flexibility in a compressed state to permit passage to the myocardial site (figs. 1-6, col. 3, lines 23-38); the stent includes a covering 30 made of expanded PTFE material (col. 5, lines 2-3) on an inner surface portion and outer surface portion of the stent (fig. 2, col. 4, lines 12-18); delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36); and expanding the stent to deploy it in the passage (fig. 5-6, col. 3, lines 34-36).

Tweden although discloses the covering (liner 30) of the stent is impregnated with a hemocompatible and anti-thrombogenic agent such as heparin (col. 4, lines 28-31), it does not explicitly disclose the coating of this agent over the covering. However, Tedeschi teaches a thromboresistant coating method in which covered medical device surfaces such as those covered with PTFE is exposed to solution of a thromboresistant such as heparin and after upon drying would produce a substrate surface containing heparin (col. 6, lines 7-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to use the thromboresistant coating method as taught and suggested by Tedeschi et al. to coat heparin over Tweden's covering 30 in the inner surface of the stent, for the purpose of providing a

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thromboresistant coating that is thin, durable and biocompatible and that may be applied in a single coating (Tedeschi, col. 2, lines 47-19).

6. Re claims 3-4, 11-12, 15-16, 18-20, 25-26, and 30-31 Tweden discloses (claims 3, 19 and 30) the covering 30 includes expanded PTFE material (col. 5, lines 2-3); (claims 4, 20 and 31) wherein the covering covers substantially all of an inner and outer surface of the stent (col. 4, lines 16-18 and 50-54, fig. 2); (claims 11-12 and 25-26) the coronary vessel is a coronary artery 82 and the heart chamber is a left ventricle 83 (fig. 1); (claims 15-16, 18) delivering the stent includes delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36).

7. Re claims 13-14 and 27-28, with respect to the limitation "partial blockage", Tweden discloses the myocardial site is distal to a coronary blockage 81 (fig. 1), which appears to be a partial blockage. Alternatively, if blockage 81 is not viewed to be a partial blockage then it would be obvious for a coronary blockage to be either total or partial blockage and in either case the device and method taught by Tweden still apply.

8. Re claims 38, 42, 45, and 48, Tweden discloses the stent includes a flared end 12 (fig. 1)

9. Re claims 10 and 24, Tweden discloses the flared end 12 is placed in the passage to face the coronary vessel (fig. 1);

10. Re claims 39, 43, and 46, Tweden teaches the step of expanding the stent to deploy it in the passage (fig. 5-6, col. 3, lines 34-36) at the myocardial site such that the flared end 12 seats around an end of the passage (fig. 1).

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11. Claims 37, 41, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden/Tedeschi and further in view of Eno et al. (6,409,697 B2).

12. Tweden/Tedeschi's device has all the claimed features except that it is L-shaped and is not substantially straight. However, Eno teaches that it is preferably for the device to have a straight implant rather than the L-shaped implant, which includes a portion to be placed within a coronary vessel and a portion to be placed within the myocardium, because the size can be reduced and shape enhanced by elimination of the vessel portion (col. 1, lines 38-55). Since the suitability of the implant for minimally invasive or percutaneous procedure is influenced by the external size and shape of the implant (col. 1, lines 51-54), the straight implant would have an advantage of providing an enhance design for reducing a likelihood of damage to a coronary vessel from a high-velocity blood flow discharge (col. 1, lines 9-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to substitute the L-shaped stent of Tweden with the straight stent of Eno, as suggested and taught by Eno, in order to implant a device for passing blood flow directly between a chamber of the heart and a coronary vessel with reduced likelihood of damage to a coronary vessel from a high-velocity blood flow discharge.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhong ' 600 teaches stents with hybrid coating for medical devices.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After-Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Quang D. Thanh
Patent Examiner
Art Unit 3764
May 6, 2004


Danton D. DeMille
Primary Examiner